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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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10/614,037

07/08/2003

Manfred Reiter

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09/29/2009

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EXAMINER

VOGEL, NANCY TREPTOW

ART UNIT

PAPER NUMBER

1636

MAIL DATE

DELIVERY MODE

09/29/2009

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary

Application No.

10/614,037

Applicant(s)

REITER ET AL.

Examiner

NANCY VOGEL

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1636

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 04 June 2009.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 34-36 and 46-66 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 34-36, 46-66 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-8508)
Paper No(s)/Mail Date _____

- 4) ☐ Interview Summary (PTO-413)
Paper No(s)/Mail Date _____
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: _____

DETAILED ACTION

Claims 34-36 and 46-66 are pending in the case.

Claim Rejections - 35 USC § 112

Claims 34-36, 46-66 are rejected under 35 U.S.C. 112, first paragraph, because the specification, while being enabling for growth of VERO cells in the medium specified in the examples, does not reasonably provide enablement for a method for producing an immunogenic composition comprising a virus or a virus antigen comprising providing a culture of any cell, or any of a list of the cell types set forth in claims 64-66, 65 and 56-58, grown in any animal protein free medium comprising soy and yeast hydrolysate. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention commensurate in scope with these claims.

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 2/4/09. Applicant's arguments filed 6/4/09 have been considered but have not been found convincing.

Applicants have argued that it would not require undue experimentation to practice the invention throughout its scope in light of methods disclosed in the specification and based on what is known in the art. Applicants argue that the claims recite media as disclosed in the specification, and culture of numerous cells, as listed on page 7, and therefore the specification provides sufficient support to meet the enablement requirement. Applicants argue that the reference

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Shubiya (US 6406909) is improperly cited since Shibuya did not use the same medium as recited in the claimed invention, since it does not exclude Insulin Human Recombinant, and may include animal proteins produced with recombinant techniques. Applicant argues that the instant claimed method avoids animal proteins and therefore Shibuya is not relevant. Applicants argue that they have set for "a few examples" and therefore the specification is enabling. Applicants argue that the enablement requirement can be satisfied through broad terminology or illustrative examples.

However, it is maintained that Shibuya is relevant for the teaching that it cannot be easily predicted whether any particular culture medium would support growth of any particular cell type, and that even when culture medium is supplemented by recombinant animal products, it cannot be predicted whether growth of a particular cell type will be supported. While it is acknowledged that Shibuya et al. discloses that without the addition of an animal derived product, no growth was observed, this does not mean that the reference is irrelevant. The reference was cited to show that there is unpredictability involved in cell culture methods, with much experimentation, without predictability, involved in determining a particular cell culture media and method that will allow a cell that is normally present in a living organism, to survive and multiply in artificial cell culture. Furthermore, applicant's arguments that the specification sets forth more than one, or "a few" examples, does not address the fact that one cell type, using one cell culture media, has been exemplified. It is maintained that merely setting forth a few examples for growth of one cell type, using one type of culture

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medium, does not provide support for the growth of any cell type, using any type of culture medium with the only requirement being that yeast and soy hydrolysates are present. There is no predictability to guide one to the choice of a particular cell culture medium, which, when supplied with yeast and soy hydrolysates, would successfully support the culture of any particular cell type. While the fact that the specification only discloses the growth of VERO cells in one particular culture medium does not in itself show that the claimed method is not enabled, the fact that one of skill in the art cannot predict whether other cell types would have the same culture requirements, and the fact that undue experimentation such as the choice of virtually infinite numbers of possible components and concentrations thereof, for a cell culture medium, would be required, show that the specification does not provide an enabling disclosure to support the scope of the claims. Therefore the rejection is maintained.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 34-36, and 46-66 are rejected under 35 U.S.C. 103(a) as being unpatentable over Price et al. (WO 98/15614) in view of Kistner et al. (US Patent 5,753,489), Luderer et al. (US P patent 4282315), Gauri et al. (US Patent

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4,322,404) and Quest International Product Information, Norwich NY, 1995, and Sheffield Pharma Ingredients, Cell Nutrition, Hydrolyzed Proteins & Yeast Extracts, Technical Manual (all previously cited).

This rejection is maintained essentially for the reasons made of record in the previous Office action, mailed 2/4/09.

Applicant's arguments filed 6/4/09 have been considered but have not been found convincing.

Applicants have argued that Price et al. does not disclose an animal protein free medium and that the examiner is improperly using hindsight reconstruction of the prior art. Applicants argue that the reference teaches the "substitution" for animal products by enzymatic digests of yeast and soy cells, and that this does not constitute a teaching of an animal product free culture medium. However, it is maintained that when one substitutes animal products with soy and yeast cell hydrolysates, one arrives at an animal free culture medium. Price et al. was cited for the teaching that generally animal products, maybe be substituted for by yeast and soy enzymatic digests. Encompassed in that teaching, would be the total substitution of said animal products. There is no teaching in the reference to contradict this. The fact that all such animal products are substituted with the disclosed soy and yeast cell hydrolysates, results in an animal free cell culture medium, is not excluded by the reference. Therefore, applicant's arguments are not found convincing. Furthermore, applicant argues that the Examiner is making a rejection under 35 USC 103 and also 35 USC 112 p.1, which is contradictory. However, It is noted that this Office Action contains

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rejections of the same claims under 35 USC 112, 1st (scope of enablement) and 35 USC 102(b) and 103(a). While these rejections may seem contradictory, they are not because each is based upon a different legal analysis, i.e. sufficiency of the disclosure of the instant application to support claims under 35 USC 112, 1st paragraph vs. sufficiency of a prior art disclosure to anticipate or render obvious an embodiment(s) of the claimed invention (See *In re Hafner*, 161 USPQ 783 (CCPA 1969)). In response to applicant's argument that the examiner's conclusion of obviousness is based upon improper hindsight reasoning, it must be recognized that any judgment on obviousness is in a sense necessarily a reconstruction based upon hindsight reasoning. But so long as it takes into account only knowledge which was within the level of ordinary skill at the time the claimed invention was made, and does not include knowledge gleaned only from the applicant's disclosure, such a reconstruction is proper. See *In re McLaughlin*, 443 F.2d 1392, 170 USPQ 209 (CCPA 1971).

Conclusion

THIS ACTION IS MADE FINAL. Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be

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calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to NANCY VOGEL whose telephone number is (571)272-0780. The examiner can normally be reached on 7:00 - 3:30, Monday - Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Christopher Low can be reached on (571) 272-0951. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/NANCY VOGEL/
Primary Examiner, Art Unit 1636

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NV

9/25/09